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10/531,664

02/23/2006

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EXAMINER

FRITCHMAN, REBECCA M

ART UNIT

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/531,664
Filing Date: February 23, 2006
Appellant(s): NAGANO ET AL.

Arnold Turk
For Appellant

EXAMINER'S ANSWER

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This is in response to the appeal brief filed 06/16/2010 appealing from the Office action mailed 05/14/2009.

(1) Real Party in Interest

The real party in interest is Tetsuo NAGANO and Sekisui Medical Co., Ltd. by an assignment from the inventors to Tetsuo NAGANO and Daiichi Pure Chemicals Co., Ltd. recorded February 23, 2006, at Reel 017284, Frame 0643 (5 pages), and by a change of name from Daiichi Pure Chemicals Co., Ltd. to Sekisui Medical Co., Ltd. recorded December 23, 2009, at Reel 023698, Frame 0483 (23 pages).

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The status of the claims is as follows:

Claim 1 is canceled, and claims 2 and 3 are pending in this application and are under appeal.

Of the pending claims, claims 2 and 3 have been finally rejected in the Final Office Action dated May 14, 2009, and are under appeal.

(4) Status of Amendments After Final

The appeal is based upon finally rejected claims. An Amendment to the Final Office Action dated May 14, 2009, was filed November 25, 2009 following a November 18, 2009 telephone interview. A first Advisory Action, dated December 21, 2009, indicated that for

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purposes of appeal the amendment filed November 25, 2009 would not be entered and claims 2 and 3 are rejected. However, a second Advisory Action, dated January 15, 2010, indicated that for purposes of appeal, the amendment filed November 25, 2009 will be entered, and claims 2 and 3 are rejected as explained in the attachment to the Advisory Action.

An amendment was filed February 9, 2010 to correct an error in claim 3. A third Advisory Action, dated February 24, 2010, indicated that for purposes of appeal, the amendment filed February 9, 2010 will be entered, and claims 2 and 3 are rejected.

On June 15, 2010, a Request for Extension of Time for five months, and a Cover Letter Submitting Terminal Disclaimer Under 37 C.F.R. 41.33 and a Terminal Disclaimer accompanied by the government fee were submitted with respect to U.S. Patent No. 7,378,282, which is used in an obviousness-type double patenting rejection. It is assumed that the Terminal Disclaimer will be entered so that the rejection based upon U.S. Patent No. 7,378,282 is moot.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

(a) Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/64664 to Nagano (using EP 1 260 580 A1 as English version) as evidenced by US 2002/0182736 A1 to Aldini et al. (hereinafter "Aldini").

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. The appellant filed a terminal disclaimer with respect to US Patent 7378282 and it was approved on 06/23/2010, hence the withdrawal of double patenting rejections.

(a) Claims 2-3 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 7,378,282

(hereinafter "the '282 patent") as evidenced by US 2002/0182736 A1 to Aldini.

(b) Claims 2-3 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5 and 13-14 of U.S. Patent No. 7,087,766 (hereinafter "the '766 patent") as evidenced by US 2002/0182736 A1 to Aldini.

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

20020182736	ALDINI	2002
EP 1 260 580	NAGANO	2-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagano (WO01/64664) as evidenced by Aldini et al. (US 2002/0182736 A1).
Examiner acknowledges that WO01/64664 is published in Japanese. Examiner assumes that the English version of WO01/64664 in the form of EP 1 260 508 A1 is

a direct translation of WO01/64664 and therefore examiner references the EP publication.

With respect to Claims 2 & 3, Nagano teaches of compounds ss-1F (Page 5, 4th reaction, right most product) and ss-3F (Page 6, second reaction, right most product) which anticipate the claimed compounds HPF and APF (Formula I). Nagano further teaches of reacting ss-1F and ss-3F with a reactive oxygen species and measuring fluorescence of a dephenylated compound produced by this reaction (which reads on instant claim 3). Nagano does not disclose a specific example using ss-1F or ss-3F to measure peroxynitrites. However, Nagano teaches that "[t]he types of reactive oxygens which are measurable by the agent of the present invention are not particularly limited." ([0020]). It is well known among those with ordinary skill in the art that peroxynitrite ion contains reactive oxygen, as evidenced by Aldini et al. Aldini et al. teaches that peroxynitrite is considered a reactive oxygen species ([0046] and [0048]). Since Nagano teaches the ability of ss-1F and ss-3F to measure unlimited types of reactive oxygen species, and since peroxynitrite is a reactive oxygen species, one of ordinary skill in the art would expect that compounds ss-1F and ss-3F would measure peroxynitrite ion with a reasonable likelihood of success.

Also, the Nagano reference teaches measuring reactive oxygen or singlet oxygen in similar situations as disclosed by the applicant, except that it does not spell out detecting peroxynitrite. However, the reference teaches detecting oxygen in similar situations. Formation of peroxynitrite is inherent and immediate by applicant's own admission (page 1, paragraph starting with peroxynitrite) in such situations as are

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present in the Nagano reference; and applicant's claimed method also detects the oxygen from peroxyxynitrite. Thus, even if the reference does not expressly state that it is measuring peroxyxynitrite, it is inherently or at least obviously measuring peroxyxynitrite.

Applicant has not disputed the fact that the reference Nagano does teach the same compounds as recited in claim 3.

Claims 2-3 are is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5 and 13-14 of U.S. Patent No.7,087,766 as evidenced by Aldini et al. (US 2002/0182736). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '766 compounds ss-1F and ss-3F anticipate the compounds HPF and APF, respectively, of Formula (I) as claimed in claims 2 and 3.

Regarding the method claim 3, one of ordinary skill in the art would expect that the compounds of '766 to react with reactive oxygen species other than the expressed examples, including the reactive oxygen species peroxyxynitrite ion. Regarding '766 patent claims 5 and 13-14, '766 does not expressly provide an example using ss-1F or ss-3F to measure peroxyxynitrites ion. However, Nagano discloses a method for measuring reactive oxygen using compounds ss-1F and ss-3F and teaches that "[t]he types of reactive oxygens which are measurable by the agent of the present invention are not particularly limited." ([0020]). It is well known among those with ordinary skill in the art that peroxyxynitrite ion contains reactive oxygen, as evidenced by Aldini et al. ([0046], [0048]). Therefore, one of ordinary skill in the art would expect that compounds ss-1F and ss-3F would measure peroxyxynitrite ion with a reasonable likelihood of Success.

(10) Response to Argument

With respect to the appellant's arguments that the instant invention allows for peroxynitrite(ONOO radical) alone to be successfully measured without measuring the presence of other free radical species(including superoxide & nitric oxide) by using the measuring reagent in the present invention(HPF & APF)(Page 13, paragraph 1, appeal brief), the examiner disagrees. The appellant also argues that the measurement of peroxynitrite is an unexpected result which the examiner also disagrees with.

The examiner disagrees that the reagents (HPF & APF) used in the instant specification/claims detect only peroxynitrite. Through examining example 1 & table 1 in the instant specification, it is clear that both HPF and APH still allow detection of other free radical species (namely superoxide O_2^- radical & NO radical) in addition to the detection of peroxynitrite. See applicant's table 1 below (from page 8 of instant specification):

Table 1			
Measured species	HPF	APF	DCFH
ONOO ⁻	120	560	6,600
O ₂ ⁻	8	6	67
NO	6	< 1	150

From this table it is clear that in the reagents used in the instant invention (HPF & APF) detect peroxynitrite, superoxide, & nitric oxide. Therefore, the reagents used in the instant specification/claims A) are not actually specific to peroxynitrite(they work on all free radical species peroxynitrite, superoxide, and nitric oxide), & B) there is no

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unexpected result(since the reagents HPF & APF also detect other free radical species- nitric oxide & superoxide in addition to peroxynitrite).

The appellant also attempts to show in their arguments/table 1 the advantage of using APF & HPF over a conventional reagent (DCFH). From the examiner's understanding of this table, there is no advantage (specifically not the claimed advantage of being specific to peroxynitrite) of the use of reagents APF & HPF since as shown by the table all three reagents HPF, APF, & DCFH) all detect superoxide, peroxynitrite, and nitric oxide in the same ratios (OONO/O₂ ratio for APF being approximately 93 while OONO/O₂ ratio for DCFH being 94).

The appellant also argues that the NAGANO reference solely teaches of the detection of free radical species & does not specifically mention peroxynitrite being a free radical which is detected. NAGANO specifically teaches, however, that, "the types of reactive oxygen species which are measurable by the agent of the present invention are not particularly limited"(paragraph 0020 of EP 1206508 A1). From the examiner's understanding, this phrase, in the least, means that the reagents used in NAGANO are not specific to one or only a few reactive oxygen species, and therefore it would be obvious to one of ordinary skill to use the NAGANO reagents on other reactive oxygen species (even ones which are not specifically named in NAGANO). The examiner uses ALDINI only as evidence to show the existence/ that peroxynitrite is a commonly known reactive oxygen species (paragraph 0046 & 0048). From this, it would be clear to one having ordinary skill in the art that the reagents in NAGANO could be used to detect most/if not all reactive oxygen species (which includes peroxynitrite).

Again, the examiner would like to point out that the reagents disclosed/claimed in the instant specification are **NOT** from what is presently disclosed specific only to peroxynitrite, but also detect superoxide and nitric oxide in addition to peroxynitrite, which is in contrast to what is currently claimed/argued.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Rebecca Fritchman

/REBECCA FRITCHMAN/

Examiner, Art Unit 1797

Conferees:

Vickie Kim

/Vickie Kim/

Supervisory Patent Examiner, Art Unit 1797

/Anthony McFarlane/